

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

**BRECKENRIDGE PHARMACEUTICAL,
INC,**

Civil Action No.: 07-CV-11114(RWS)

Plaintiff,

vs.

MIDLAND HEALTHCARE, LLC.

Defendant.

**MEMORANDUM OF LAW IN OPPOSITION TO PLAINTIFF BRECKENRIDGE
PHARMACEUTICAL, INC., MOTION FOR SUMMARY JUDGMENT**

Burrell Regenstreich, LLC, Bruce Regenstreich (BR 2046), 110 Wall Street, Eleventh Floor, New York, New York 10005, Tel: 212-567-8590, Fax-212-567-2630 Attorneys for Defendant Midland Healthcare, LLC ("Midland"), respectfully submits this memorandum of law in opposition to Plaintiff Breckenridge Pharmaceutical, Inc. ("Breckenridge"), Motion for Summary Judgment, as follows:

PRELIMINARY STATEMENT

In this breach of contract matter the plaintiff's claims that the defendant Midland did not perform any services is inaccurate at best. As will be shown below, and in the accompanying Declaration of Raman Kapur (sworn to on February 26, 2008) (the Kapur Declaration), there are numerous, significant, genuine issues of material facts that preclude the grant of summary judgment in this matter. In addition, the plaintiff's motion is premature in that it was filed at a time when, according to the explicit terms of the contract at issue, the "cure" period for any alleged breach of contract had not yet expired. Material issues of fact exist so as to warrant a denial of Breckenridge's motion for summary judgment in its entirety.

STATEMENT OF FACTS

The Statement of Facts have already been stated in the Plaintiff's Rule 56.1 Statement of Undisputed facts and in the accompanying Declaration of Raman Kapur's Rule 56.1 (b) Counter-Statement of Undisputed Facts. Therefore, defendant herein will not state the facts again but respectfully refer the Court to such documents for the contents therein.

ARGUMENT

SUMMARY JUDGMENT MUST BE DENIED

A. The Standard of Review on a Breach of Contract Claim

Summary Judgment is only appropriate when there is no "genuine issue of material fact" and the undisputed facts warrant judgment for the moving party as a matter of law. Fed. R. Civ. 56 (c); *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 106 S. Ct. 2505, 91 L. Ed. 2d 202 (1986). In addressing a motion for summary judgment, "the court must view the evidence in the light most favorable to the party against whom summary judgment is sought and must draw all reasonable inferences in [its] favor." *Matsushita Elec. Indus. Co. Ltd. v. Zenith Radio Corp.*, 475 U.S. 574, 587, 106 S. Ct. 1348, 89 L. Ed. 2d 538 (1986) (emphasis added). A Court may grant summary judgment only if it determines that there are no genuine issues of material fact based on a review of the pleadings, depositions, answers to interrogatories, admissions on file and affidavits. *Celotex Corp. v. Catrett*, 477 U.S. 317 (1986). Whether any disputed issue of facts exists is for the Court to determine. *Baldernan v. United States Veterans Admin.*, 870 F. 2d 57, 60 (2d Cir. 1989). Once the nonmovant has adduced evidence of a genuine issue of material fact, its "allegations [will be] taken to be true and [it] will receive the benefit of the doubt when [its] assertions conflict with those of the movant. *Samuels v. J. Mockry, et. al.*, 77 F. 3d 34, 26 (2nd Cir. 1996).

Further, the moving party bears the burden of demonstrating the absence of a genuine issue of material fact. *United States v. All Funds*, 832 F. Supp. 542, 550-551 (E.D.N.Y. 1993). Particularly where, as in the instant matter, a contract is involved, summary judgment is appropriate only where the language of the contract is clear and unambiguous, and reasonable persons could not differ as to its meaning. See *Fulton Generation Assocs. V. Niagara Mohawk Power Corp.*, 84 F. 3d 91, 98 ((2d Cir. 1996). Contract language is unambiguous when it has "a definite and precise meaning, unattended by danger of misconception in purport of the [contract] itself, and concerning which there is no reasonable basis for a difference of opinion" *Hunt Ltd. V. Lifschultz Fast Freight, Inc.*, 889 F. 2d. 1274, 1277 (2d Cir. 1989) (quoting *Breed v. Ins. Co. Of North America*, 46 N.Y. 2d 351, 413 N.Y.S.2d 352, 385 N.E. 2d 352, 385 N.E. 2d 1280 (1978) (emphasis added).

B. The Terms of the Instant Contract, as well as Breckenridge's Own Conduct, will Unambiguously Show that:

1. Midland has performed pursuant to the terms of the contract and have not breached the contract.
2. Midland was denied the opportunity to "cure" any alleged breach and, therefore Plaintiff can not, prior to such "cure" period ending, allege a breach of contract, and

Annexed hereto, and made part of this Opposition is Section 7 of the ANDA Development, Manufacture and Supply Agreement entered into between the Plaintiff and defendant on, or about January 26, 2007. (Exhibit "A", the Agreement").

The pertinent language of Section 7: TERM AND TERMINATION OF AGREEMENT, sub-section 7.2 (b) thereto, states:

"Breckenridge may terminate this Agreement for Midland's breach of its material obligations hereunder; material breach is defined to include (i) failure to accomplish certain Milestones in accordance with Exhibit B, of the ANDA Development, Manufacture, and Supply Agreement, (ii) provide reports in

accordance with Section 2.3, or comply with audits and inspections or provision of documents in accordance with Section 3.4, or (iii) or material breach of any representations or warranties contained herein, at any time by giving at least sixty (60) days prior written notice of termination to Midland, ***and so long as Midland fails to remedy the breach to the reasonable satisfaction of Breckenridge prior to the expiration of the sixty (60) day notice period provided the breach is capable of being cured within the 60 day period***”.

Emphasis supplied. (Relevant portions attached as Exhibit “B” hereto)

Further in Section 7.2 (b), the aforesaid Agreement states , “If Breckenridge exercises its option to terminate this Agreement in accordance with the provisions of this Section 7.2(b), Breckenridge’s obligations to pay for development services shall cease upon completion of the notice period, if applicable, and Midland will prepare a reconciliatory billing for actual services rendered.”

Clearly Breckenridge understood that the above notice provision was a pre-condition to any claimed “breach of contract” since their moving papers also included a “Notice of Termination” letter dated November 30, 2007, which was sent “pursuant to Section 7.2 of the Agreement” via overnight delivery to Midland’s Chairman and Vice Chairman. (Termination letter attached as Exhibit “C”). In fact, the termination letter alluded to “post-termination” rights and obligations as contained in the Agreement.

Plaintiff’s termination letter alleged that defendant failed to “timely comply with agreed upon milestones” and, “failure to provide at least two (2) consecutive monthly reports and other reports requested by Breckenridge.” There is no indication that these alleged breaches could not have been cured within a sixty day period.

Plaintiff, rather than afford an opportunity to cure within sixty days of the date of the termination letter, immediately filed the within lawsuit.¹

C. As previously argued, summary judgment is a harsh remedy and should

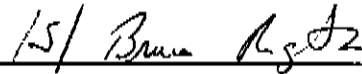
¹As stated, the termination letter is dated November 30, 2007. The sixty day cure period would have ended January 30, 2008. Plaintiff herein filed suit on December 7, 2007, a mere seven days after the termination letter was sent.

only be granted if there are no genuine issues of material fact and the undisputed facts warrant judgment for the moving party as a matter of law. There has been no discovery in this matter, depositions or interrogatories and the declaration of Raman Kapur raise genuine issues of material facts that preclude the granting of summary judgment, included, but not limited to the work performed incident to the Milestones contained in the subject Agreement, the failure of the Plaintiff to provide the necessary sixty day cure period prior to any breach, and the amount of damages the plaintiff may claim, subject to the monies expended by Midland in furtherance of the project at the time the contract is terminated.

CONCLUSION

For all of the aforementioned reasons the motion for summary judgment should be, in all respects, denied

Dated: New York, New York
February 26, 2008



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212-440-4400
Fax-212-440-4401

CERTIFICATION

I hereby certify that an original and one copy of the within document has been electronically filed with the United States District Court, Southern District of New York and that a copy of same has been served upon all interested parties within the period of time allowed in accord with R 1:6-4 and 4:6-1.

The within document has been served within the time prescribed by the Rules of Court or as extended by Stipulation between the parties. The matter in controversy is not the subject of any other action pending in any court or of a pending arbitration proceeding, nor are the names known of any other party who should be brought in this action.

The matter in controversy is not the subject of any other action pending in any court or of a pending arbitration proceeding, nor are the names known of any other party who should be brought in this action.

I hereby certify that the foregoing statements made by me are true. I am aware that if any of the foregoing statements made by me are wilfully false, I am subject to punishment.

BURRELL REGENSTREICH, LLC
Attorneys for Defendant(s) MIDLAND
HEALTHCARE, LLC

By: /s/ Bruce Regench
BRUCE REGENSTREICH

Dated: February 26, 2008

Our File No.: 22.NM6956
BURRELL REGENSTREICH LLC
219 E. BERGEN PLACE
RED BANK, NEW JERSEY 07701
732-212-8400

Attorneys for Defendant(s), MIDLAND HEALTHCARE, LLC.

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AFFIRMATION OF SERVICE

BRUCE REGENSTREICH, ESQ. affirms as follows:

I am an attorney duly licensed to practice law before the Courts of the State of New York. I am not a party to the action, I am over 18 years of age and I work at 110 Wall Street, Eleventh Floor, New York, New York 11201.

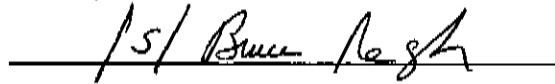
I hereby affirm to be true, under the penalty of perjury, that on January 17, 2008 I served a true copy of the annexed Opposition to the Motion for Summary Judgment by electronic delivery and by mailing same in a sealed envelope with postage prepaid in an official depository of the U.S. Postal Service and Certified Mail, Return Receipt Requested, and by Regular Mail, addressed to:

C. Randolph Ross, Esq.
Crowell & Moring, LLP
153 E. 53rd Street, 31st Floor
New York, New York 10022
212-895-4200
Fax-212-223-4134

Kristi A. Davidson, Esq.
BUCHANAN INGERSOLL ROONEY PC
Attorneys for Plaintiff
One Chase Manhattan Plaza-35th Floor
New York, NY 10005-1417

Dated: New York, New York
February 26, 2008

Yours, etc.

A handwritten signature in dark ink, appearing to read "15/ Bruce Regenstreich", is written over a horizontal line.

Bruce Regenstreich
BURRELL REGENSTREICH, LLC
Attorneys for Defendant (MIDLAND
HEALTHCARE, LLC



Breckenridge Pharmaceutical, Inc.

November 30, 2007

VIA OVERNIGHT DELIVERY AND ELECTRONIC MAIL

Email: ram.kapur@patmedia.net

Paul Sudhakar
Vice Chairman
Midland HealthCare LLC
1201 Douglas Avenue
Kansas City, Kansas 66108

Raman Kapur
Chairman
Midland HealthCare LLC
791 Alexander Road
Princeton, New Jersey 08540

**Re: *Notice of Termination*
 Midland-Breckenridge ANDA Development and Supply Agreement
 *Dated January 26, 2007 ("Agreement")***

Gentlemen:

In accordance with our numerous emails previously sent to Midland and discussions during our September 12, 2007, meeting at your office, pursuant to Section 7.2 of the Agreement, Breckenridge hereby confirms the termination of the Agreement due to Midland's failure to timely comply with agreed-upon milestones and for failure to provide at least two (2) consecutive monthly reports and other reports requested by Breckenridge. Breckenridge will advise Midland shortly of its intentions concerning any post-termination rights and obligations as contained in the Agreement. Breckenridge reserves the right to claim additional events of breach against Midland, as well as other rights associated with this termination, whether or not contained in the Agreement.

Sincerely,

A handwritten signature in black ink, appearing to read 'Eugene L. Kim', is written over a horizontal line.

Eugene L. Kim
General Counsel

cc: Larry Runsdorf – President
 Larry Lapila – Vice President, Business Development

Eugene L. Kim, General Counsel
Breckenridge Pharmaceutical, Inc., Connecticut Office, 15 Massirio Drive, Suite 201, Berlin, CT 06037
Phone: 860-828-8140 • Direct Fax: 860-760-6499 • Email: ekim@bprx.com
www.breckenridgepharma.com

PHASE I: Preformulation			
		Total Cost	Handling
1	Assay Method for Drug Product , development purpose	\$2,500.00	\$125.00
2	API sourcing and acquisition	\$3,000.00	
	Subtotal	\$5,500.00	\$125.00
	PHASE I total		\$5,625.00

PHASE II: Formulation Development (R & D) and Dissolution Testing			
		Total Cost	Handling
1	Misc. equipment change parts needed for Liquid Line	\$4,500.00	\$0.00
2	Formulation development work at Midland (10 days work) @ \$1500/day	\$20,000.00	\$1,000.00
3	Develop initial test methods for pilot studies	\$3,500.00	\$175.00
4	R & D Packaging for machine check and etc	\$2,500.00	\$125.00
	Sub total	\$30,500.00	\$1,300.00
	PHASE II- Total		\$31,800.00

PHASE III: Process Development			
		Total Cost	Handling
1	Non GMP prototype batch (3) production	\$2,500.00	\$125.00
2	Product development testing	\$2,000.00	\$100.00
3	Establishment of IPC, tests etc	\$2,500.00	\$125.00
	Sub total	\$7,000.00	\$350.00
	PHASE III- Total		\$7,350.00

PHASE IV: Analytical Method Development and Validation			
		Total Cost	Handling
1	Stability indicating method development for assay and impurities	\$7,000.00	\$350.00
2	Validation of methods using final formulation developed in phase III	\$20,000.00	\$1,000.00
3	Analytical method development report	\$2,000.00	
	Sub total	\$29,000.00	\$1,350.00
	PHASE-IV- Total		\$30,350.00

PHASE V: Pilot GMP Batch			
		Total Cost	Handling
1	Establishment of IPC and Finished Product Controls beyond phase III (if necessary)	\$500.00	\$25.00
2	Preparation of batch records for non GMP batch	\$1,500.00	
3	Raw materials testing and release	\$11,000.00	\$550.00
4	Production of prototype on GMP batch	\$4,000.00	\$200.00
3	In Process Testing of prototype non GMP batch for standard tests	\$2,500.00	\$125.00
4	Packaging (pilot GMP batch)	\$1,500.00	\$75.00
5	Final release testing of non GMP with Cof A	\$0.00	\$0.00
6	Cleaning Verifications (methods, validation, testing etc)	\$2,500.00	\$125.00
7	Innovator reference samples and testing	\$1,000.00	\$50.00
	Sub total	\$24,500.00	\$1,150.00
	PHASE V Total		\$25,650.00
	Development Report	\$2,000.00	
	Grand Total		\$102,775.00